

Risk of cancers

RINVOQ® may potentially increase your risk of developing cancers particularly skin cancer.

Let your doctor know if you notice any change in the appearance of an area on your skin, or notice any new growth on your skin.

Risk of a hole in your bowel

RINVOQ® may increase your risk of a hole in your bowel especially if you have Crohn’s disease. Tell your doctor straight away if you have unexplained or unexpected stomach pain.

Show this card to any healthcare professional involved in your medical care – for example, your dentist or an emergency doctor.

For any side effects please report to the Medicines Authority at www.medicinesauthority.gov.mt/adrportal or contact AbbVie’s local representative V. J. Salomone Pharma Ltd. At +356 99644126.

Your name:

Consultant’s name – who prescribed RINVOQ®:

Consultant’s phone number:

The date you started RINVOQ®:

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Patient Card

Keep this card with you (or caregiver) all the time

Safety Information about RINVOQ® (upadacitinib) for patients

- This card contains important safety information you should be aware of – before and during treatment with RINVOQ®.
- Read the patient information leaflet for more information.

Risk of infections

RINVOQ® may make an existing infection worse or increase the chance of you getting a new infection – for example tuberculosis (TB), shingles or viral hepatitis.

Tell your doctor straight away if you notice signs of infection, such as:

- Fever, sweating, chills, weight loss, or a cough that won't go away – these may be signs of TB.
- Painful skin rash with blisters – this may be a sign of shingles.
- Feeling tired or short of breath – this may be a sign of pneumonia.

Tell your doctor if:

- You have been recently diagnosed with TB or you have ever had TB.
- You have recently been in close contact with someone who has TB.

Vaccines – used to help prevent infections

Live vaccines (for example influenza vaccine by nasal spray, varicella, measles/mumps/rubella) should not be given during RINVOQ® treatment, or just before starting RINVOQ® treatment.

Before being given any vaccines, talk to your doctor – they will know which vaccines you should not be given before or during treatment with RINVOQ®.

Risk of heart disease

RINVOQ® may potentially increase your risk of heart disease.

Tell your doctor straight away if you notice symptoms such as chest pain or tightness since this may be a symptom of heart disease.

Risk of blood clots in veins or lungs

Blood clots in veins or lungs have been observed with RINVOQ®.

Tell your doctor straight away if you get signs of blood clots in veins or lungs, such as a painful swollen leg, shortness of breath, or chest pain.

Contraception, pregnancy, and breast-feeding

RINVOQ® must not be taken during pregnancy.

- Use effective contraception while taking RINVOQ® – and for 4 weeks after your last dose. Talk to your doctor about effective contraception.
- Tell your doctor straight away if you wish to become pregnant, or if you become pregnant.
- Tell your doctor straight away if your child has her first period (menstrual bleeding) while taking RINVOQ®.
- Do not breast-feed while using RINVOQ®.